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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,817	10/03/2003	Paul J. Bobrowski	PHMC0745-023	3270

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/678,817	BOBROWSKI, PAUL J.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-32* is/are pending in the application.

4a) Of the above claim(s) *18-24 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 06 January 2006 is acknowledged and has been entered.

Newly submitted claims 18-24 and 32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 18-24 and 32 are drawn to a product - a rehydration composition; whereas the previously examined claims were drawn to a method - a method of treating symptoms of diarrhea in a mammal. Please note that there are numerous ways to treat symptoms of diarrhea in a mammal (including symptoms associated with dehydration) which do not require a composition comprising the ingredients recited within the rehydration composition of claims 18-24 and 32.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-24 and 32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 25-31 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There does not appear to be adequate support within the instant specification for various newly recited claim limitations. For example, the Examiner could find no support within the instant specification concerning a method of rehydrating a mammal via administering a composition comprising an extract of a species of *Croton* plant latex having the instantly recited relative UV absorbency range - i.e., reduced 50% relative to unextracted plant latex, and an extract of *Uncaria* plant material having the instantly recited relative alkaloid concentration - i.e. less tan about 0.5 mg/g relative to unextracted *Uncaria* plant material, in combination with the other recited ingredient(s), as instantly claimed.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, first paragraph for the reasons set forth above.

Applicant failed to point to where such newly recited claim limitations are found within the instant disclosure within the response filed 06 January 2006. Accordingly, the newly recited claim limitations, as set forth above, are deemed new matter. Applicant is required to cancel the new matter, or alternatively to particularly point to where adequate support for such claim limitations are found within the instant specification, in the reply to this Office Action.

Claims 25-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is rendered vague and indefinite because it is unclear as to what the newly recited claim limitations are actually defining with respect to a method of rehydrating a mammal via administering a composition comprising an extract of a species of *Croton* plant latex having the instantly recited relative UV absorbency range - i.e., reduced 50% relative to unextracted plant latex, and an extract of *Uncaria* plant material having the instantly recited relative alkaloid concentration - i.e. less tan about 0.5 mg/g relative to unextracted *Uncaria* plant. material. That is, since no support was found for such limitations, it is unclear as to what these limitations are actually defining including, e.g., how and in what way such relative measurements and/or determinations were made with respect to relative UV absorbency of the latex material and/or relative alkaloid concentration of the *Uncaria* plant material extract.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

Claims 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the admitted state of the art, Illek et al. (IDS Ref. - 12/2000), Miller et al. (IDS Ref - Am. J. Physiol. Gastrointest. Liver Physiol., 2000), and Inomata (US 2001/0012524), for the reasons set forth in the previous Office action which are restated below.

As readily admitted by Applicant, the administration of an oral rehydration solution (ORS) that contains effective amounts of glucose, sodium bicarbonate, potassium (in the form of a salt) and sodium (in the form of a salt) is well known in the prior art to be the gold standard for the treatment of diarrhea and that the instant invention relates to a combination of the prior art anti-diarrheal ORS plus the botanical component(s) instantly claimed. Further, as readily admitted by Applicant, latex sap (which would intrinsically contain less than 10% water) extracted from the bark of Croton species, as well as decoctions (which read upon extracts) from the bark of *Uncaria* species, have both been used in the prior art to treat gastrointestinal distress and, further, that the latex extracted from various *Croton* species (aka Sangre de grado) is well known in the prior art to be an effective agent in managing diarrhea (see, e.g., page 1, paragraph [003] - page 4, paragraph [010] of the instant specification).

Illek et al. and Miller et al. also each beneficially teach the use of latex from *Croton* species, as well as extracts thereof (such as SP-303 and/or SB-300), for treating diarrhea (see entire documents).

Inomato beneficially discloses that an extract of *Uncaria* has long been known as an effective medicine for treating diarrhea (see, e.g., page 1, paragraph [0011]).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat diarrhea in a mammal by administering result-effective amounts of ORS in combination with an extract from either of the claimed plant species based upon the admitted state of the art and the beneficial teachings provided by the cited references, as discussed above, with respect to the well known anti-diarrheal activity such ingredients were known to possess. Accordingly, it would have been obvious to combine the instantly claimed

ingredients (e.g., ORS plus one or both of the claimed botanical extract ingredients) for their known benefit since each is well known in the art for the same purpose (i.e., treating diarrhea) - the idea for combining them flows logically from their having been used individually in the prior art, and to use the combination for that purpose - such as within the instantly claimed method. Please note that the recited functional properties instantly claimed would be intrinsic to the cited prior art *Croton* and *Uncaria* extracts discussed above. Further, such anti-diarrheal extract preparations would also intrinsically read upon a dietary supplement, a food, a food additive, and/or one or more of the other pharmaceutical forms instantly claimed. The adjustment of particular conventional working conditions (e.g., determining result-effective amounts of such ingredients; adding a conventional agent such as a coloring, flavoring, or sweetening agent such as sucrose therein, and/or providing such an anti-diarrhea preparation within one of various commonly-employed pharmaceutical forms) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the admitted state of the art (as instantly disclosed) and the cited references - as discussed above, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments concerning the above USC 103 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicant argues that the cited references do not teach or suggest using an extract of a species of *Croton* plant latex

having the instantly recited relative UV absorbency range - i.e., reduced 50% relative to unextracted plant latex, and an extract of *Uncaria* plant material having the instantly recited relative alkaloid concentration - i.e. less tan about 0.5 mg/g relative to unextracted *Uncaria* plant material, in combination with the other recited ingredient(s) to rehydrate a mammal, as instantly claimed. However, because it is unclear by the instant specification as to what these newly recited relative claim limitations are actually defining (see USC 112, first and second paragraph rejections above), they have not been afforded patentable weight at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655